Control Number SAC-17-41674

JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Description of Action Being Approved: This proposed action is for the issuance of an Indefinite Delivery Requirements, Firm-Fixed-Price (FFP) contract on an application for Brand-Name description basis for FibroScan® equipment with Controlled Attenuation Parameter (CAP) software.

3. Description of Supplies/Services including Estimated Values.

FibroScan® utilizes Vibration-Controlled Transient Elastography (VCTE) technology that appears to be the approach of choice to determine the degree of fibrosis. This has been validated in over 1,200 publications on the various aspects of effectiveness, efficacy and accuracy of VCTE to help aid Physicians in their treatment of Liver Disease. This technology has been endorsed by various professional societies including the American Association for the Study of Liver Diseases, the American Gastroenterological Association, and the European Association for the Study of the Liver. The specific components and quantities covered by this Brand-Name Justification are as follows:

Description/Part Number	Quantity
FibroScan® 502 Touch Package - M/XL Probe, Cap Software, Install, Training, and 1 Year Premium Service/PK502C02	90
FibroScan® 530 Compact Package - M/XL Probe, Cap Software, Install, Training, and 1 Year Premium Service/PK502C03	90
M Probe	75
XL Probe	75
CAP Software	50
Premium Service 1 Year	550

The ordering period will be for 60 months. The Government estimated cost for this requirement is detailed in the table below:

Period of Performance	Estimate
60 Months	[redacted]

FibroScan® works by emitting a shear wave, which may feel as a slight vibration on one's skin, into the liver and measure the speed of transmission, which is a function of degree of fibrosis. FibroScan®, through the VCTE technology, calculates the speed of this shear wave to give healthcare providers an immediate measure of the stiffness of the liver. In addition, FibroScan® with Controlled Attenuation Parameter (CAP) software calculates a surrogate marker that correlates with hepatic steatosis.

The FibroScan® system with VCTE was approved by the Food and Drug Administration (FDA) for use in the United States during April 2013 and the CAP Software was approved during June 2015. FibroScan® is being utilized at over 50 VA Medical Centers, all of which were procured independently either directly from the manufacturer or through the authorized distributor. Paris based Echosen™ is the manufacturer of FibroScan® and is the only manufacturer that can fulfill this requirement.

4. Statutory Authority Permitting Other Than Full and Open Competition.

The statutory authority permitting other than full and open competition is 41 U.S.C.3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1(c) entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements; Application for Brand-Name Descriptions".

5. Rationale Supporting Use of Authority Cited Above:

Market research was conducted and the details of which are in the market research section (Section 8) of this document. This effort did not yield any additional sources other than who is identified in Section 8 that can meet the Government's requirements. A meeting was held with the HHRC Working Group on 22 February 2017 to better understand the capabilities of the products. From this meeting it was determined that FibroScan® is the only FDA Approved equipment for non-imaging based fibrosis assessment using the required VCTE technology. The unique features of FibroScan® which set this technology apart from all other devices are as follows:

a. FibroScan® is a Point of Care (POC) tool that is performed in the outpatient clinic by non-radiologists and non-technologists. Other competitors in the elastography space market their tool as a software upgrade to existing radiology-based ultrasound equipment. Ultrasound-based elastography requires an Ultrasound Technologist and is a tool that is deployed and controlled through the Radiology service.

b. FibroScan® VCTE based elastography is the only technology with extensive scientific validation that is cited as a first line test for fibrosis assessment in viral hepatitis that is supported by clinical practice guidelines. The American Association for the Study of Liver Diseases (AASLD) only recommends FibroScan® testing, the World Health Organization (WHO) has FibroScan® based VCTE elastography listed in the clinical practice guidelines, and the United

States Center of Medicare & Medicaid Services (CMS) has assigned a Current Procedural Terminology (CPT) code only to this technology.

c. Ease of Use - Use of FibroScan® does not require assistance of the ancillary radiology department and can be used by any clinical care provider at the bedside; no sonographer, technician, or radiologist is needed to perform the test or interpret results. The picture generated on the screen of the FibroScan® is a quality assessment tool only (not a radiographic image) that shows measurements with quantitative and real time results for POC testing.

6. Description of Efforts Made to Solicit Offers from as many potential sources as practical.

The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed; however, all future requirements will be handled on a case-by-case basis to determine any future acquisition strategy.

There is no competition anticipated for this acquisition. Additionally, the proposed action will be synopsized on the Federal Business Opportunities Page in accordance with FAR 5.201. Section 8 of this document addresses the market research to support efforts made to solicit from others.

7. Determination of Fair and Reasonable Cost.

In accordance with FAR 15.305(a) (1), normally, competition establishes price reasonableness; however, since this is a Brand-Name acquisition, competition may be extremely limited to Echosens the Original Equipment Manufacturer (OEM) and FDS as they are the only distributors of FibroScan ® in the United States. Therefore, the prices quoted may be evaluated to determine whether they are fair and reasonable by any one or combination of the following:

a. VA will ask the vendor to provide their commercial catalog pricing, as offered to their most preferred customers. VA will also independently develop, separate from the IGCE, a target price based on the lowest price in the market and discounts for VA volume and other factors, i.e., the "Lowest Defensible Price." The potential awardee will be required to justify increases over this price to satisfy government determination that the offer price is "fair and reasonable."

8. Description of the Market Research conducted and results.

Market research established that the Government's need may be met by a type of item or service customarily available in the commercial marketplace that would meet the definition of a commercial item IAW FAR 10.002. The Government conducted market research using the following methods:

a. Inventories of the Requiring Agency: Not applicable. The program office indicated the need could not be met with neither Supply Fund Stock nor VA Excess stock.

b. Excess from other agencies (see Subpart 8.1): Not applicable. The program office indicated the need could not be met with VA Excess stock.

c. Federal Prison Industries, Inc.: (see Subpart 8.6): Search of UNICOR's website http://www.unicor.gov using the Search using the term "Non-Invasive VCTE Equipment" resulted in zero results.

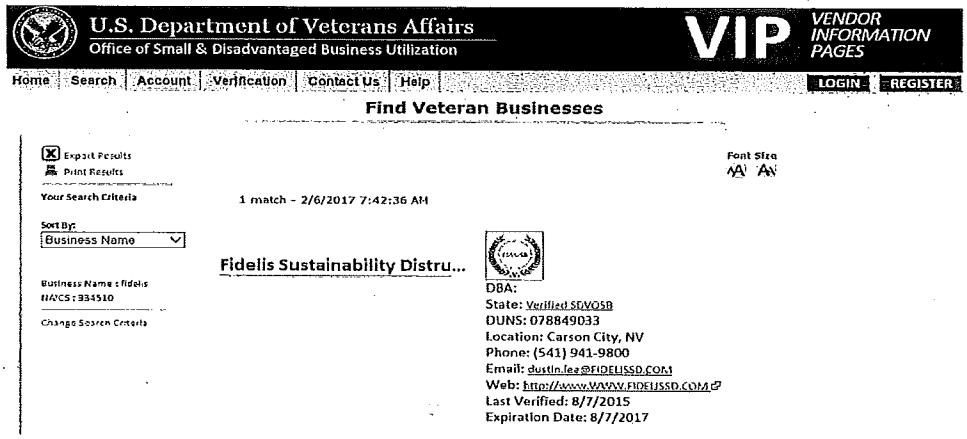
d. Supplies which are on the Procurement List maintained by the Committee for Purchase from People Who Are Blind or Severely Disabled (see Subpart 8.7): Search of Ability One website: http://abilityone.gov through their product category for medical and dental supplies using the term "Non-Invasive VCTE Equipment" provided zero results.

e. Wholesale supply sources: such as stock programs of the General Services Administration (GSA) (see 41 CFR 101-26.3), the Defense Logistics Agency (see 41 CFR 101-26.6), the Department of Veterans Affairs (see 41 CFR 101-26.704), and military inventory control points: Not applicable.

f. A review of GSA Advantage, or Federal Supply Schedule (FSS), Schedule 65 IIA Medical Equipment and Supplies yielded no FSS holders capable of supplying Non-Invasive VCTE Equipment.

g. IAW with VAAR 810.001 and 810.002, a query of the Veterans Information Pages (VIP) database (VetBiz) was conducted to identify potential Veteran Owned (VOSB) and Service Disabled Veteran Owned Small Businesses (SDVOSB) that were capable of providing Non-Invasive VCTE Equipment. NAICS 334510, PSC 6525; ELECTROMEDICAL AND ELECTROTHERAPEUTIC APPARATUS MANUFACTURING yielded 93 potential VIP certified SDVOSB/VOSB's.

A Request For Information (RFI) (VA119-17-N-0139) was also published on 27 January 2017, in FedBizOpps for 10 days. Only one company submitted information by the closing date and time that is capable of meeting the requirement; Fidelis Sustainability Distribution (FDS).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Office of Small & Disadvantaged Business Utilization
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1 match - 2/6/2017 7:42:36 AM
Sort By: Business Name
Business Name : fidelis
NAICS : 334510
Change Search Criteria
Fidelis Sustainability Distru...
DBA:
State: Verified SDVOSB
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Location: Carson City, NV
Phone: (541) 941-9800
Email: dustin.lea@FIDELISSD.COM
Web: http://www.WWW.FIDELISSD.COM
Last Verified: 8/7/2015
Expiration Date: 8/7/2017

FDS's approach to meet the requirement included Non-Invasive VCTE Equipment FibroScan® manufactured by Echosens™. The manufacturer is a French high-technology company specializing in non-invasive diagnostic products and services for hepatology. FibroScan® has been validated in over 1,200 publications on the various aspects of effectiveness, efficacy and accuracy to help aid Physicians in their treatment of Liver Disease. The RFI and Market Research reinforces FDS's claims of being the sole SDVOSB authorized distributor of FibroScan® products in the United States. The Echosens™ North America office located in Waltham, Massachusetts also confirmed via email on April 3, 2017 that Echosens and FDS are the only distributors of FibroScan ® in the United States.

[redacted]

[redacted]

[redacted]

9. Any other facts supporting the use of other than full and open competition.

Current research has found that the only other technology to come forward as a potential competitor is the [redacted] The HHRC Working Group confirmed that this is not a POC testing tool as it requires the services of an Ultrasound Technician to perform the testing and it captures an image that then needs to be interpreted by a radiologist. Furthermore, Ultrasound Elastography is not currently supported as a fibrosis assessment tool in clinical practice guidelines.

10. Interested Sources

No other sources expressed an interest in the acquisition other than FDS and [redacted].

11. Actions to Remove Barriers to Future Competition.

The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed. All future requirements will be handled on a case-by-case basis to determine any future acquisition strategy.

12. Certifications:

a. TECHNICAL/REQUIREMENTS PERSONNEL:

I certify that the supporting data under my cognizance, which are included and form the basis of this justification, are accurate and complete to the best of my knowledge and belief.

[redacted]

Date: _____ Signature: [redacted]

b. CONTRACTING OFFICER:

I certify that this justification is accurate and complete to the best of my knowledge and belief. Furthermore, I determine that the anticipated price to the Government for this action will result in fair and reasonable prices paid based on the rationale outlined in Section 7 of this justification.

Date: _____ Signature: [redacted]

Brian Shepard
Contracting Officer
Strategic Acquisition Center

c. COUNSEL:

I have reviewed this justification and find it adequate to support other than full and open competition and deem it legally sufficient.

Date: _____ Signature: [redacted]

Staff Attorney
Office of General Counsel

13. Approval

In my role as the head of the procuring activity described in Section 1 of this document, and based on the foregoing justification, I hereby approve the acquisition of FibroScan® on an other than full and open competition, application for brand name description basis pursuant to the statutory authority cited in Section 4 above. My approval is subject to availability of funds, and provided that the property and services herein described have otherwise been authorized for acquisition.

Date: 5/17/2017 Signature: [redacted]

Phillip Christy
Head of Contracting Activity
Strategic Acquisition Center